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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/524,716	03/14/00	WOLF	B 6671.US.01

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ROSS PRODUCTS DIVISION OF ABBOTT LABORAT
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EXAMINER

CHOI, F

ART UNIT**PAPER NUMBER**

1616

DATE MAILED:

06/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application N .	Applicant(s)	
	09/524,716	WOLF ET AL.	
	Examiner	Art Unit	
	Frank I Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: Please update reference to copending application. Further, since Applicant only referenced the copending application by inventor(s) name and a title (Examiner notes that the inventive entity and title are not exactly the same as U.S. Pat. 6,248,375), Examiner requests that Applicant provide evidence that the update does not constitute new matter. For future reference, Applicant, in order to more clearly reference a copending application prior to it being assigned an application serial number, should also use an internal docket number which can then be updated to the application number.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-24 are indefinite because the two-component carbohydrate mixture may contain more than two components.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hicks et al. (Abstract).

Hicks et al. expressly discloses a 42% high fructose corn syrup falling within the scope of applicant's claims.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980).

Claims 1-17, 20, 21, 23, 24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kaufman.

Kaufman expressly discloses a food bar weighing 33 grams containing corn starch, fructose, soy protein isolate, maltitol syrup, crisp rice (rice flour malt extract, rice bran), polydextrose, cocoa, non-fat milk, glycerine, canola oil, natural flavors, gum arabic and lecithin, providing 120 calories of which about 64% were from carbohydrates, 17% from protein and 19% from fat, containing 5 g of protein, 2.5 g of fat and 22 g of carbohydrates of which 5g were cornstarch, 17 grams were more rapidly adsorbed carbohydrates, including, 6 g of fructose, 3 g of maltitol and remainder provided primarily by the polydextrose and peanuts, and 90 mg of

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sodium and 90 mg of potassium, which was fed to diabetics and was effective in reducing the incidence of fluctuations in glucose levels and hyperglycemia after eating (Columns 9, 10).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re May*, 197 USPQ 601, 607 (CCPA 1978). See also *Ex parte Novitski*, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,248,375 (Gilles et al.) in view of Kaufman (U.S. Pat. 5,843,921).

Claims 1-19 of Gilles et al. disclose a nutritional bar comprising a source of fat, a source of protein and a two part carbohydrate system containing fructose and a nonabsorbent carbohydrate source wherein the carbohydrate system comprises about 45% to 90%, the fat source comprises less than about 30% and the protein comprises about 10 to about 25%, of the

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total calories and a method of providing nutrition to an individual with diabetes comprising enterally administering said composition.

Kaufman teaches that fructose and slowly metabolized complex carbohydrate, such as uncooked corn starch, helps to stabilize glucose levels and an example containing fructose, corn starch, polydextrose, fat sources and protein source is taught which was effective in reducing the incidence of fluctuations in glucose levels and hyperglycemia after eating. (Column 2, lines 25-40, Columns 9, 10).

The difference between the claims of Gilles et al. and the claimed invention is that the claims of Gilles et al. do not expressly disclose a carbohydrate system or a nutritional product, containing a two component carbohydrate mixture about 5 to about 50 wt/wt % of a source of fructose and about 50 to about 95 wt/wt% of a digestible glucose polymer source. However, the prior art amply suggests the same as it known that fructose and sources of glucose polysaccharides are suitable for feeding diabetics and preventing fluctuations in glucose levels. As such, it would have been well within the skill of one of ordinary skill in the art to modify the claims of Gilles et al. with the expectation that any ratio of a mixture of fructose and source of glucose polysaccharides would be effective for the same.

Therefore, the claimed invention, as a whole, would have been obvious variation of the claims of Gilles et al. to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

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Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

FIC

June 26, 2001



JOHN PAK
PRIMARY EXAMINER
GROUP 1600

